

SOP#: RPS-16

Key Study Personnel Changes

Version #: 3.2

Next Review Date: 05/2024

Approved Date: 05/2022

Review Interval Period: Biennial

NCI Clinical Director Signature:

POLICY

The NIH Institutional Review Board (IRB) allows for administrative changes in Key Study Personnel (KSP) (also referred to as “Study Personnel List”) for a protocol. “Key Study Personnel” is a term used in iRIS, the IRB management system, for research staff including investigators, research nurse coordinators, referral contact(s), and collaborators. Changes in personnel (aside from the Principal Investigator, which must be processed as a full protocol amendment) can be submitted to the IRB using the Amendment form in iRIS.

The Principal Investigator is responsible for ensuring that all research staff required to be on the KSP Page are listed and assigned the appropriate roles.

PURPOSE

Describe the steps to notify the IRB of administrative changes in key study personnel for a protocol using the KSP Page. These steps are performed by the Protocol Support Office (PSO) manager assigned to the protocol.

RESOURCES

- NIH Office of Intramural Research Policies & Guidance [website](#)
 - Policy 300 - Investigator Responsibilities
 - Policy 102 – Investigator Conflict of Interest and Government Royalties
 - Policy 109 – Coverage Under the NIH FWA
- CCR Policies/Standard Operating Procedures [website](#)
 - RPS-14 - *Submission of the Personal Financial Holdings Form to the Institute/Center Deputy Ethics Counselor*

PROCEDURES

STEP 1: Create a Protocol Key Study Personnel (KSP) Page

- **For new studies:** Using the KSP Page template from the PSO Share Drive, include a listing of all personnel (including collaborators per CCR PSO policy) involved in the conduct of the protocol. Include identification of the roles of each investigator. Send to PI and study coordinator to confirm accuracy.

- **For existing studies:** To initially create a KSP Page for an existing protocol, an amendment submission will be required to move the personnel from the title page of the protocol onto a clean KSP Page. Send to PI and study coordinator to confirm accuracy.

Note: The NIH Principal Investigator (PI) will be listed on both the protocol title page and the KSP Page.

- If personnel are NOT changed: Mention in the IRB cover memo that personnel are being moved from the protocol title page for administrative purposes to create a KSP Page and that changes to staff are not being made.
- If personnel are added and/or deleted: Personnel changes will be shown as tracked in the MS Word version of the KSP Page. Mention in the IRB cover memo that personnel are being moved from the protocol title page for administrative purposes to create a KSP Page and that staff are being added/deleted.
- **When non-NIH federal employees (e.g., FDA, Walter Reed) will be involved with all activities taking part at the NIH site:** Before the investigator can be listed on KSP, an Individual Investigator Agreement (IIA) must be requested and executed by OHSRP. To obtain an IIA, the following steps must be completed:
 - Confirm the protocol(s) on which the individual will be involved, activities, and the individual's current employment, and submit this to OHSRP.
 - Note: See example email template with questions in the PSO SOP RPS-16 working file.
 - OHSRP will draft and execute the IIA once all requirements are met.
 - Create an "Agreements" subfolder in the KSP folder of the working files and save the IIA.

STEP 2: Amend an Existing Protocol KSP Page

Using the clean MS Word version of the most recently approved KSP Page, track all changes for staff being added/deleted and update the document version date. Verify accuracy of all information on the KSP Page and revise, as needed. Be sure to check NIH Enterprise Directory (NED) for classification (Employee, Contractor, Fellow, Special Volunteer). Send to PI and study coordinator to confirm accuracy.

STEP 3: Verification of Required Training

For all KSP Page submissions: Ensure that all investigators are in compliance with required training. KSP Page cannot be submitted to the IRB until verification of training has been confirmed.

For CCR staff: If investigators are not in compliance, please contact the CCR Director of Office of Education and Compliance.

For non-NIH KSP included on the NIH study team: These individuals may need to have their CITI account mirrored for training to be reflected in iRIS. See email template/instructions in the PSO SOP RPS-16 working file.

STEP 4: Submit KSP Page to the Deputy Ethics Counselor (DEC), if applicable

Attach the clean KSP Page to the DEC request form and submit to the IC DEC via iRIS. See CCR SOP RPS-14 for more information.

STEP 5: Submit the Protocol KSP Page in iRIS

- **For initial studies:** KSP Page is submitted to the IRB as a clean document attached to the Initial Review Submission Form. DEC clearance must be attached, if applicable.

Note: Ensure that all study personnel (PI, AI and other research staff) are listed on the Study Application at the time of Initial Review submission.

- **For existing studies:** The KSP Page is submitted to the IRB using the Amendment Form in iRIS. List all key study personnel changes in the Amendment form, except for collaborators as they are not listed in iRIS.
 - KSP changes may be submitted as a stand-alone action or along with other actions.
 - If newly added personnel do not have an iRIS account, one will be requested by the PSO manager via iRIS Help Desk Support web page (this will need to be done prior to iRIS submission):
(<https://iris.helpdesk.nih.gov/jira/servicedesk/customer/portal/3/group/4>)
 - Complete the Amendment form and attach the following:
 - Clean KSP Page
 - Tracked KSP Page (if applicable)
 - DEC Outcome Letter-approval (if applicable)
 - Study Application (if applicable)

STEP 6: Assign Signatures in iRIS

- KSP at time of Initial Review: Route as an attachment to the Initial Review Submission Form to PI and Branch Chief (or Clinical Director if PI is Branch Chief) for signature.
- KSP changes at time of Amendment: Route the Amendment form to the study PI for signature.